NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 20, 2015

The Honorable Mike Callton
Chairman, Health Policy Committee
Room 519, House Office Building
Lansing, Michigan 48909

Re: HB 4437 – Substitution of Interchangeable Biological Drug Products

Dear Chairman Callton and Members of the Health Policy Committee:

On behalf of our members that operate approximately 1,547 pharmacies in the state of Michigan, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on HB 4437. In an effort to enable pharmacists to continue providing patients with the most cost-effective medications, chain pharmacy supports updating state laws to allow for the substitution of interchangeable biological drug products consistent with current substitution practices for generic drugs. As such, we write to express our support of HB 4437.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries.

NACDS applauds Representative Ken Yonker for introducing a bill that paves the way for the use of biosimilars and, eventually, for the use of interchangeable biologic products. As you may know, the Food and Drug Administration (FDA) has yet to issue guidance on the requirements to obtain interchangeability designation. And while we now see biosimilars entering the market, it is unlikely we will see the imminent entrance of interchangeable biological products to the market. Nevertheless, HB 4437 lays groundwork to enable critical patient access to lower-cost medications and prudently avoids creating roadblocks for the use of biosimilars and the eventual use of interchangeable biologic products.

That said, we do know what the FDA is working towards in its efforts to designate interchangeability. We know from the Public Health Services Act, under section 351-(k)(4), an "interchangeable" biological product will be a product that has been shown to

be biosimilar to the reference product, and can be expected to produce the same clinical result as the reference product in any given patient. Further, it must be shown that "for a biological product that is administered more than once to an individual the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch."[1]

If a biosimilar does not meet that stringent standard, it will not be considered interchangeable. However, if it does meet that future FDA standard, any additional requirements will only serve to discourage their use and to impede patient access. According to Commissioner Margaret Hamburg, the FDA is concerned that "[e]fforts to undermine trust in these products are worrisome and represent a disservice to patients who could benefit from these lower-cost treatments."[2] In short, special substitution requirements for interchangeable biologic products would be unwarranted.

Notification requirements also create distractions from the important communications already initiated by pharmacists when there are pressing healthcare issues to address. For example, pharmacists commonly reach out to prescribers regarding potential drug interactions, patient allergies to medications, and formulary issues. It is important to maintain focus on patient care issues that need resolution, and not to inundate prescribers with irrelevant information.

We can look forward to interchangeable biological products being listed in the so called Purple Book. This will be a definitive resource for physicians and pharmacists alike to know what is, and is not, interchangeable. The formal name of this document is *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.* Just as FDA has done for approved small molecule drugs with the Orange Book, the agency has developed the Purple Book to list the various approved biologic drugs - inclusive of both approved innovator products and approved biosimilar products. Consistent with the format of the Orange Book, the Purple Book has a mechanism to identify biosimilars that have been deemed interchangeable by FDA and would be, therefore, substitutable.

HB 4437 not only wisely paves the way for patient access to interchangeable biological products, but will save the State of Michigan significant money. According to a 2014 report published by the Rand Corporation, national savings from the use of biosimilars could total close to $44.2 billion over ten years.[3] Let us not miss the same opportunity

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[1]http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411424.htm

[2] Remarks of FDA Commissioner Margaret Hamburg at the GPhA Annual Meeting (February 22, 2013)

[3] http://www.rand.org/pubs/perspectives/PE127.html

that has saved trillions of dollars with the substitution of generic small molecule medicines. [4]

NACDS thanks you for considering our support for this important bill. We welcome the opportunity to work with you and other policymakers to continue promoting patient access to more affordable versions of biologic medications. Please do not hesitate to contact me at 847-905-0555 or jkurzman@nacds.org if we can be of further assistance.

Sincerely,

Joel Kurzman

Joel Kurzman
Director, State Government Affairs

[4] GPhA, Generic Drug Savings in the U.S. (September 2014)